Attachment VI

Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Boston Scientific Corporation (BSC)
iSight™ Imaging Catheter

Submitted by:

Boston Scientific Corporation
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Date prepared:

January 20, 2006

Proprietary Name:

BSC iSight™ Imaging Catheter

Common Name(s):

Ultrasound Diagnostic Imaging Catheter
Diagnostic Intravascular Catheter (74DQO)
Diagnostic Ultrasonic Transducers (90ITX)

Classification Name(s):

Diagnostic Intravascular Catheter, 21 CFR Part 870.1200 (74DQO)
Diagnostic Ultrasonic Transducer, 21 CFR Part 892.1570 (90ITX)

Predicate Device(s):

The BSC iSight™ Imaging Catheter is substantially equivalent to the following device:

Product	510(k)	Clearance Date
Atlantis™ SR Pro^2 Coronary Imaging Catheter	K050577	March 30, 2005

Description of the Device

The iSight™ imaging catheter consists of two subassemblies:

- Catheter body
- Imaging core

The catheter body is comprised of three sections:

- Distal section - Guidewire lumen and Imaging Core lumen
- Proximal section - Imaging Core lumen only
- Telescoping section - Imaging Core lumen only

The distal section of the iSight™ catheter body has a guidewire lumen and an imaging core lumen. The 1.3 cm long guidewire lumen with tapered entry profile provides access into the femoral artery via a 0.36 mm (0.014") guidewire. To enhance pushability and trackability, the guidewire lumen is lined with polytetrafluoroethylene (PTFE) and a hydrophilic coating [Bioslide™ BL] is applied to the distal section of the catheter body. For fluoroscopic visibility within the vasculature, a radiopaque (RO) marker is embedded in the catheter tip at 0.5 cm from the distal tip. To enhance flexibility, the catheter sheath gradually tapers from 2.5F at the proximal bond, to 1.5F at the distal section.

The proximal section is comprised of a single lumen tube with attached molded strain relief. For navigational purposes, an insertion depth indicator is located on the proximal section 100 cm from the distal tip and corresponds to the length of a 100 cm guide catheter.

The working length of the iSight™ catheter assembly is comprised of the distal and proximal sections and measures 135 cm. The iSight™ catheter is 5F guide catheter compatible.

The telescoping section remains outside of the guide catheter and allows for 15 cm of linear translation of the imaging core within the catheter body. It also contains a flush port with a one-way valve, which is used to displace air near the

transducer prior to insertion into the patient. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use. The telescope section has 16 gold marks, spaced at 1-cm increments, to indicate imaging core position during manual pullback of the imaging core.

The imaging core is composed of a flexible, rotating drive cable with an outward looking 40 MHz ultrasonic transducer at the distal end. The transducer, in the fully advanced position, is located 1.7 cm from the catheter distal tip. An electro-mechanical connector interface at the proximal end of the imaging core makes the connection to the Motor Drive Unit (MDU). The MDU-Catheter interface consists of an integrated mechanical drive hub and electrical connection. The iSight™ catheter is compatible with the MD-4 and MD-5 Motor Drive Units.

The iSight™ catheter is compatible with the ClearView Ultra™, Galaxy™, Galaxy ^{2} ™, and iLAB™ systems.

Intended Use/Indications for Use:

The iSight™ Imaging Catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Device Technology Characteristics an Comparison to Predicate Device:

The BSC iSight™ Imaging Catheter utilizes the same basic catheter design as the predicate device, the BSC Atlantis SR Pro^{2} Coronary Imaging Catheter, (cleared in March 30 2005). This device has the same intended use, the same operating principal, incorporates the same basic catheter design, and is packaged using the same materials and processes as the predicate device.

The modifications to the iSight™ Imaging Catheter include, a change to the hydrophilic coating, reduction to the imaging window profile, distal housing profile, entry profile, crossing profile, and guidewire lumen. Material change to

the male telescope tubing, guidewire lumen lining and hub O-ring. Reduction in distance from transducer to catheter tip. Addition of gold marks on the telescoping section, and a new molded strain relief. In addition, the shelf life will be 11 months, and the iSight™ catheter will be sterilized using Ethylene Oxide (EO) sterilization method. These modifications are made to enhance the performance of the catheter.

Non-clinical Test Results:

Bench testing, biosafety testing, and package validation, demonstrate that the iSight™ Imaging Catheter exceeds the performance requirements, and is safe and effective for its intended use.

Bench Testing:

Bench testing was performed to evaluate the physical integrity, functionality, and performance of the catheter. Testing included dimensional testing, bond tensile testing, and a variety of performance testing of the sheath and telescoping assembly, the imaging core assembly, and of the final sterile device.

Biological Safety Testing:

The iSight™ Imaging Catheter was subjected to a series of biocompatibility tests per EN ISO 10993, and microbiological assessment, which included bioburden, pyrogen/endotoxin, sterility assurance, and latex testing. The results of the biosafety testing demonstrate that the catheter is acceptable for its intended use.

Acoustic Output Testing:

The iSight™ Imaging Catheter was tested for acoustic output as described in the FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 30, 1997).* Acoustic Output test results for the iSight™ Imaging Catheter are below the FDA Track 1 limits.

Packaging Validation:

Package validation was performed on the catheter package design per EN 868, to validate the integrity of the packaging system. Test results demonstrate that the packaging met all of the pre-determined acceptance criteria.

Conclusion:

The BSC iSight™ Imaging Catheter utilizes the same design features and has the same intended use/indications for use as its predicate device, the Atlantis™ SR Pro^2 Coronary Imaging Catheter. The tests support a determination of substantial equivalence of the modified device, the iSight™ Imaging Catheter to its predicate device.

Confidential

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2006

Boston Scientific Corporation
c/o Mr. Robert Z. Phillips
Manager, Regulatory Affairs
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Re: K060175
Trade Name: iSight™ Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: February 22, 2006
Received: February 23, 2005

Dear Mr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____

Device Name: **Boston Scientific Corporation, iSight™ Imaging Catheter**

Indications for Use: The iSight™ Imaging Catheter is intended for ultrasound examination of coronary intravascular pathology ONLY. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription Use ___X_____ AND/ OR Over the counter Use _____
(Part 21 CFR 801 Subpart D) Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060175

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